

The European added value of health system cooperation to ensure access to innovative medicines and technologies

The contribution made by the Maltese Presidency of the Council of the European Union January-June 2017 to strengthen health system cooperation

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Educational aims

- To increase awareness about the role played by the Maltese Presidency of the Council of the European Union
- To appreciate the potential of increased cooperation between health systems as a mechanism to address critical health system challenges
- To gain an understanding of the state of play in regional country cooperation to improve access to innovative medicines and technologies

Key words

Health systems, European Union, International Cooperation, Health technology, joint procurement

Abstract

Between January and June 2017, Malta held the Presidency of the Council of the European Union (EU). One of its thematic priorities was Structured Cooperation between health systems. Evidence for strengthened cooperation in the areas of procurement of health technologies and delivery of highly specialised services was presented and discussed in a series of meetings. Council Conclusions were elaborated and an ambitious cooperation declaration between Southern European countries in the area of access to innovative medicines was signed. This article describes the rationale for these linked activities as a means to support European health systems in addressing critical challenges that cannot be tackled by Member States acting alone. These cooperation initiatives are important in the light of the evolving debate on the Future of Europe and the role that health policy should play in the European Union post 2020. Malta, as a small Member State with an open market, is often exposed earlier and more harshly to the impacts of market and environmental changes on its health system. It can therefore play an important role in scanning the horizon for potential impacts and proposing appropriate policy responses at European level.

Introduction

In January 2017, for the first time in history, Malta took up the Presidency of the Council of the EU. As is customary, Malta presented its thematic priorities for discussion and debate. In the health sector, one of the two main priorities presented was that of 'Structured Cooperation between Health Systems'.¹ This was defined as "Voluntary and organized cross-border activity between health care sector actors (e.g. governments, health agencies, providers, professional bodies, funders, educational institutions and others)".² Article 168(7) of the Treaty of the EU makes it clear that when it comes to health systems, Member States are in the driving seat and Union action shall complement the efforts of Member States.³ Traditionally, there have been serious tensions between Member States and the EU on issues related to health systems at EU level.⁴ The Maltese Presidency by proposing a voluntary approach, took into consideration the existing tensions whilst attempting to propose a solution that would allow those Member States who wish to do more together to do so in an effective manner with continuity, structure and support from the European institutions. This multi speed Europe approach is one of the options put forward for consideration on the Future of Europe White Paper by the Juncker's European Commission as Europe deliberates on its future post 2020 and post Brexit.⁵

Rationale

The Maltese Presidency chose to focus upon improving health systems cooperation with a view to finding ways to enhance access to innovative medicines, technologies and highly specialised services for European citizens. In its approach, the Presidency sought to emphasise the word voluntary when talking about structured cooperation since following the experience of the patients' rights and cross-border directive, the need to promote the idea of moving away from a one size fits all approach in the health sector was acknowledged. Increasing cross-border health system cooperation was proposed as one of the solutions that can be used to address commonly experienced challenges arising due to circumstances beyond the control of national policy more effectively. The rationale considered that cooperation with other health systems may lead to enhanced efficiency thereby contributing towards the health system sustainability objective.

The Maltese health system is well placed to steer this discussion at a European level for the following reasons. Cross border cooperation is an intrinsic characteristic of the Maltese health system with long-standing practical experience in both structured patient mobility (e.g. patients travelling overseas for treatment of rare diseases) and structured professional mobility (for specialist training purposes).⁶ Secondly the Maltese health system with its small market characteristics has been faced with challenges in securing affordable access to innovative medicines for cancer and rare diseases, but this issue is now mainstream on the European (global) policy agenda and therefore a window of opportunity for concrete action is available.

Process

In order to construct an informed debate, the Maltese Presidency commissioned the production of two policy briefs by the European Observatory on Health Systems and Policies to answer the following questions:

- **How can structured cooperation between countries address health workforce challenges related to highly specialized health care?**²
- **How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe?**⁷

The Presidency, through the Ministry for Health, organised a series of meetings where the above topics were discussed. These included a workshop on Structured Cooperation between Health Systems, an informal meeting for Directors of Pharmaceutical Policy, the meeting of Competent Authorities for Pricing and Reimbursement of Medicines and the Pharma Round Table of Health Minister with Industry. These items were also on the agenda of the Informal Health Ministers meeting as well as the EPSCO Council where Council Conclusions were presented for adoption. Under the Maltese Presidency, eight EU Member States (Cyprus, Greece, Ireland, Italy, Malta, Romania, Portugal, Spain) signed up to the Valletta declaration.⁸ In this declaration, these Member States agreed to cooperate to be in a position to better guarantee patient access to innovative medicines and therapies whilst ensuring health system sustainability. In order to achieve this objective, the Member

States agreed to establish a technical committee to explore voluntary cooperation in areas including; sharing information, identifying best practices, horizon scanning, price negotiations and joint procurement. The values of trust, loyalty, solidarity and transparency were underlined as being key to the success of this initiative.

Discussion

Health systems are currently facing a 'perfect storm' with multiple challenges producing a strong force that is challenging the status quo and traditional way of funding and organising health services. Changes in information technology (IT), changes in citizen and patient expectations, the new medicines and technology pipeline, genetic therapies, changes in payment systems and changes in provider configurations are some of the key issues that are coinciding to produce a serious effect on access and sustainability of European health systems. Furthermore, the nature of developments in medicine and the evolution of the pharmaceutical market means that mechanisms that may have worked in the past to secure access at sustainable prices will no longer continue to produce the desired results. As a consequence, it appears that there is a clear added value for health systems to work more closely together. The following areas emerge specifically as focus areas in which cross border cooperation can be strengthened: collation of data, evidence and knowledge in the post-marketing/ procurement phase, new ways of funding – new financial instruments (bonds system, data for discounts, grouping of countries to enable negotiations for larger populations and increase bargaining power).⁷ These considerations are particularly relevant for the areas of rare diseases and personalised health care.

Member States have shown interest in coming together in groups to try and address

the issue of access to innovative medicines more cost-effectively. A number of agreements have been signed in past months including the BENELUXA, Baltic, Visegrad and during the Maltese Presidency the Valletta group of Southern European countries, including Cyprus, Greece, Italy, Malta, Portugal, Spain joined by Ireland and Romania. The expectation is that by pooling capacities and bargaining power, Member States would be better able to address the market asymmetry between industry and governments, particularly for smaller Member States. This of course will depend upon the willingness of the pharma industry to engage in meaningful dialogue. In this sense, the adoption of terms of reference for a more permanent forum between Member States and industry achieved through the efforts of the Maltese Presidency is an important step in this process.

The adoption of Council Conclusions on Encouraging Member States driven Voluntary Cooperation between Health Systems provides a framework within which several actions can be developed in the coming years.⁹ The following are amongst the key priorities identified:

- Better anticipation of the impact of new medicines and technologies on health systems through more coordinated horizon scanning
- An emphasis on the monitoring during the post-marketing phase, to evaluate the outcomes, including the impact, that adoption of innovative health technologies has on patient and on health systems
- Exchange information to increase transparency and improve the leverage of individual Member States' in negotiations with industry

As discussions on the role of the future of Europe unfold, it is important to ensure that the public health objectives and health system dimension remain firmly embedded in the

Key points

- Between January and June 2017 Malta took up the Presidency of the Council of the EU
- Improving health systems voluntary cooperation to enhance access to innovative medicines, technologies and highly specialised services for European citizen was a key priority
- Eight countries signed the Valletta declaration to cooperate to better guarantee patient access to innovative medicines and therapies whilst ensuring health system sustainability
- The adoption of Council Conclusions on *Encouraging Member States driven Voluntary Cooperation between Health Systems* provides a strong legacy for the Maltese Presidency

context of promoting pharmaceutical policy and industry within the European Union. In this way, it will be possible to strike the much-needed balance between promoting the European Union as a hub for innovation and industrial growth alongside assurance of equitable access to this innovation by all European Union citizens irrespective of where they reside.

Conclusion

Developments in the medicines pipeline and changes to the medicines regulatory framework are placing increased pressure on health systems to rethink their approach to ensure sustainable access to innovation. This issue is being dealt with at an international level through several fora. The Maltese Presidency, through its policy proposals and discussions has made an important contribution in taking this agenda forward within the European Union¹⁰ and has left a strong legacy upon which further work can be carried out.¹¹

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